

Application Serial No. 10/554,290
Amendment dated 3 March 2008
Reply to Office Action mailed 3 December 2007

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims

Claim 1 (Currently Amended): A pharmaceutical composition comprising:

~~an effective amount of a β (1-3) β (1-4) glucan composition consisting essentially of at least about 75% β (1-3) β (1-4) glucan having a particle size of less than 0.2 μm , less than 10% ash impurities, less than 10% protein impurities and less than 5% lipid impurities, and~~
~~an effective amount of a botanical extract, or a pharmaceutically active agent.~~

Claim 2 (Original): The pharmaceutical composition according to claim 1, wherein the composition comprises the botanical extract, and wherein the botanical extract is an extract of Guarana, *Ginkgo biloba*, Kola nut, Goldenseal, Golo Kola, *Schizandra*, Elderberry, St. John's Wort, Valerian and *Ephedra*, black tea, white tea, java tea, garlic oil, fiber, green tea, lemon oil, mace, licorice, onion oil, orange oil, rosemary, milk thistle, *Echinacea*, Siberian ginseng or *Panax ginseng*, lemon balm, *Kava kava*, matte, bilberry, soy, grapefruit, seaweed, hawthorn, lime blossom, sage, clove, basil, curcumin, taurine, wild oat herb, oat grain, dandelion, gentian, aloe vera, hops, cinnamon, peppermint, grape, chamomile, fennel, marshmallow, ginger, slippery elm, cardamon, coriander, anise, thyme, rehmannia, eucalyptus, menthol, schisandra, withania, cowslip, lycium, or passion flower.

Claim 3 (Original): The pharmaceutical composition according to claim 2, wherein the botanical extract is an extract of oat grain.

Application Serial No. 10/554,290
Amendment dated 3 March 2008
Reply to Office Action mailed 3 December 2007

Claim 4 (Withdrawn): The pharmaceutical composition of claim 3, wherein the botanical extract comprises avenanthramide.

Claim 5 (Withdrawn): The pharmaceutical composition according to claim 1, wherein the composition comprises the pharmaceutically active agent, and wherein the pharmaceutically active agent is selected from the group consisting of beta-sitosterol, caffeine, cafestol, D-limonene, kabweol, nomilin, oltipraz, sulphoraphane, tangeretin, folic acid, and menthol.

Claim 6 (Withdrawn): The pharmaceutical composition according to claim 1, wherein the composition comprises the pharmaceutically active agent, and wherein the pharmaceutically active agent is selected from the group consisting of an antihistamine, a decongestant, a corticosteroid, a non-steroidal anti-inflammatory drug, a bronchodilator, a vasodilator, such as nitroglycerin, and a local anaesthetic.

Claim 7 (Withdrawn): The pharmaceutical composition of claim 6, wherein the vasodilator is nitroglycerin.

Claim 8 (Original): The pharmaceutical composition according to claim 1, wherein the β (1-3) β (1-4) glucan is derived from a cereal grain or a part of the cereal grain.

Claim 9 (Original): The pharmaceutical composition according to claim 8, wherein the cereal is selected from the group consisting of a cultivar of barley, a cultivar of oat, a cultivar of wheat, a cultivar of rye, a cultivar of sorghum, a cultivar of millet, a cultivar of corn, and a mixture thereof.

Claim 10 (Canceled).

Claim 11 (Currently Amended): The pharmaceutical composition according to claim ~~10~~ 1, wherein the β (1-3) β (1-4) glucan composition has a purity of at least about 92%, and contains less than 3.5% ash impurities, less than 3.5 % protein impurities, and less than 1% lipid impurities.

Claim 12 (Currently Amended): The pharmaceutical composition according to claim ~~10~~ 1, herein the cereal β -glucan composition has a clarity value of from about 5 to about 100 NTU.

Claim 13 (Currently Amended): The pharmaceutical composition according to claim 1, wherein the β (1-3) β (1-4) glucan composition is produced according to a method of isolating a β (1-3) β (1-4) glucan composition from a milled cereal grain or a milled part of the cereal grain, the method comprising:

(i) extracting the milled cereal grain or the milled part of the cereal grain with an alkaline solution having a value of pH of between 9 to 10 for a period of time of about 15 to about 45 minutes to produce an extract containing at least about 0.4 weight percent β (1-3) β (1-4) glucan;

(ii) removing insoluble material, and removing particulate material having a particle size of greater than about 0.2 μm from said extract to produce a purified extract comprising β (1-3) β (1-4) glucan having a particle size of less than 0.2 μm wherein the step of removing particulate material comprises using filtering out material having a particle size of greater than about 0.2 μm from said extract by microfiltration to produce the purified extract comprising β (1-3) β (1-4) glucan having a particle size of less than 0.2 μm as a filtrate;

(iii) adding from about 10% to about 25% (w/w) 20% (vol/vol) of a C₁-C₄ alcohol to the purified extract to precipitate the β (1-3) β (1-4) glucan composition, and

(iv) isolating the β (1-3) β (1-4) glucan composition.

Application Serial No. 10/554,290
Amendment dated 3 March 2008
Reply to Office Action mailed 3 December 2007

Claim 14 (Currently Amended): The pharmaceutical composition according to claim 13, wherein ~~in said step of adding (step iii) in said method, about 10% to about 20% (w/w) of an~~ ~~the~~ alcohol is selected from the group consisting of methanol, ethanol and isopropanol, ~~is used to precipitate the β (1-3) β (1-4) glucan from said purified extract.~~

Claim 15 (Currently Amended): The pharmaceutical composition according to claim 14, wherein ~~the alcohol about 10% to about 20% (w/w) of~~ ~~is~~ ethanol ~~is used to precipitate the β (1-3) β (1-4) glucan from said purified extract.~~

Claim 16 (Currently Amended): The pharmaceutical composition according to claim 13, wherein said step of removing particulate material in said method further comprises the following steps prior to the step of microfiltration:

one, or more than one step of adding a flocculant, a coagulant or both ~~a~~ the flocculant and ~~a~~ the coagulant to said extract to coagulate particulate material having a particle size of greater than about 0.2 μ m, and removing coagulated material from said extract; and

~~digesting starch material in said extract; and~~

~~filtering out particulate material having a particle size of greater than about 0.2 mm from said extract to produce a purified extract.~~

Claim 17 (Original): The pharmaceutical composition according to claim 16, wherein in said step of digesting in said method, said starch material is digested with an enzyme.

Claim 18 (Original): The pharmaceutical composition according to claim 17, wherein prior to digesting said starch material, said alkaline solution is neutralized.

Claim 19 (Original): The pharmaceutical composition according to claim 18, wherein following the digestion of said starch material in said method, said enzyme is inactivated.

Application Serial No. 10/554,290
Amendment dated 3 March 2008
Reply to Office Action mailed 3 December 2007

Claim 20 (Original): The pharmaceutical composition according to claim 19, wherein said enzyme is inactivated by acidifying the neutralized solution.

Claim 21 (Original): The pharmaceutical composition according to claim 17, wherein said enzyme is an amylase.

Claim 22 (Original): The pharmaceutical composition according to claim 21, wherein said amylase does not require a calcium cofactor.

Claim 23 (Original): The pharmaceutical composition according to claim 13, wherein the cereal is selected from the group consisting of a cultivar of barley, a cultivar of oat, a cultivar of wheat, a cultivar of rye, a cultivar of sorghum, a cultivar of millet, a cultivar of corn, and a mixture thereof.

Claim 24 (Currently Amended): The pharmaceutical composition according to claim 13, wherein the pH of the alkaline solution used in said method is from about 9.9.25 to about +0.9.75.

Claim 25 (Canceled).

Claim 26 (Original): The pharmaceutical composition according to claim 13, wherein said step of adding (step iii) in said method is conducted at a temperature of from about 1°C to about 10°C.

Application Serial No. 10/554,290
Amendment dated 3 March 2008
Reply to Office Action mailed 3 December 2007

Claim 27 (Currently Amended): The pharmaceutical composition according to claim 13, wherein said method further comprises one, or more than one step of dissolving the isolated β (1-3) β (1-4) glucan in an aqueous solution, precipitating the β (1-3) β (1-4) glucan by adding about 10% to about ~~25% (w/w)~~ 20% (vol/vol) of the C₁-C₄ alcohol to the aqueous solution, and isolating the β (1-3) β (1-4) glucan.

Claim 28 (New): A pharmaceutical composition consisting essentially of:
a β (1-3) β (1-4) glucan composition consisting essentially of at least about 75% β (1-3) β (1-4) glucan having a particle size of less than 0.2 μ m, less than 10% ash impurities, less than 10% protein impurities and less than 5% lipid impurities,
a botanical extract, or a pharmaceutically active agent, and
a pharmaceutically acceptable diluent or carrier.

Claim 29 (New): The pharmaceutical composition according to claim 28, wherein the β (1-3) β (1-4) glucan composition has a purity of at least about 92%, and contains less than 3.5% ash impurities, less than 3.5 % protein impurities, and less than 1% lipid impurities.

Claim 30 (New): A pharmaceutical composition consisting of:
a β (1-3) β (1-4) glucan composition consisting essentially of at least about 75% β (1-3) β (1-4) glucan having a particle size of less than 0.2 μ m, less than 10% ash impurities, less than 10% protein impurities and less than 5% lipid impurities,
a botanical extract, or a pharmaceutically active agent, and
a pharmaceutically acceptable diluent or carrier.

Application Serial No. 10/554,290
Amendment dated 3 March 2008
Reply to Office Action mailed 3 December 2007

Claim 31 (New): The pharmaceutical composition according to claim 30, wherein the β (1-3) β (1-4) glucan composition has a purity of at least about 92%, and contains less than 3.5% ash impurities, less than 3.5 % protein impurities, and less than 1% lipid impurities.